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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------------|------------------|
| 10/763,632 | 01/23/2004 | James R. Lawter | ORA5002USACNT1 (J&JO-103U) | 7747 |
| 23122 | 7590 | 03/21/2007 | | |
| RATNERPRESTIA P O BOX 980 VALLEY FORGE, PA 19482-0980 | | | EXAMINER BUMGARNER, MELBA N | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3732 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/21/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/763,632

Applicant(s)

LAWTER ET AL.

Examiner

Melba Bumgarner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41, 47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 28-35, 47 and 48 is/are rejected.
- 7) ☒ Claim(s) 22-27 and 36-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on January 5, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent Number 6,682,348 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Martin (6,083,002). Martin discloses an apparatus 10 for dispensing material comprising a barrel 12 including a body portion and a tube portion, the tube portion extending from the body portion and including a tip 20 configured for being deformed to at least one different cross-sectional geometry (column 4 line 47); and a plunger 22, at least a portion of the plunger slideably housed within the barrel.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-21, 28-34, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brizzolara et al. (5,236,355) in view of Martin. Brizzolara et al. disclose an apparatus 2 for dispensing material comprising a barrel 10 including a body portion and a tube portion, the tube portion extending from the body portion and including a tip 7; and a plunger 4, at least a portion of the plunger slideably housed within the barrel and a quantity of dry particles 9, at least a portion of the dry particles within the tip; however, they do not show a tip configured for being deformed. Martin teaches an apparatus including a tip 20 configured for being deformed to at least one different cross-sectional geometry (column 4 line 47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Brizzolara et al. to have the tip of Martin to be able to place the tip at a particular location to dispense the composition in view of Martin. Brizzolara et al. show the dry particles comprising at least one therapeutic agent of tetracycline, doxycycline, or minocycline (column 8 line 41). The dry particles comprise an effective amount of the therapeutic agent, the agent dispersed in a dry matrix comprising biocompatible and biodegradable polymer and the particles have a diameter of about 0.1 to 1000 microns (column 5 line 56). Brizzolara et al. show the therapeutic agent comprising from about 0.00001 to about 50 parts by weight per 100 parts by weight of the particles. Brizzolara et al. show the polymer comprising the limitations as claimed (column 7 line 52). Brizzolara et al. show the polymer becomes tacky upon contact with water (column 8 line 67). Brizzolara et al. show the barrel and plunger comprises olefin homopolymer of polypropylene (column 11 line 33). The agent includes minocycline hydrochloride (column 11 line 43). Brizzolara et al. show a removable closure 8. Brizzolara et al. show the apparatus enclosed in an aluminum-laminate pouch (column 11 line 13), sterilizable package, and barrel

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and plunger formed with radiation sterilizable materials (column 11 line 49). It is would have been an obvious matter of choice to one of ordinary skill in the art as to a known component being resealable. It would have been obvious to one of ordinary skill in the art as to the change in configuration to be circular and oval.

Allowable Subject Matter

6. Claims 22-27 and 36-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicant's arguments filed January 5, 2007 have been fully considered but they are not persuasive. The prior art alone or in combination show the limitations as claimed. The limitation of "a tip configured for being deformed" is claimed broadly and met by the prior art; further "to at least one cross-sectional geometry different from its initial cross-sectional geometry" is met at least in longitudinal cross-sectional geometry and probable at the plane of the bending.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melba Bumgarner whose telephone number is 571-272-4709. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached at 571-272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melba Bumgarner
Primary Examiner